

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label designation "Bitter Tonic" was false and misleading since, in order to derive benefit from a bitter tonic, it should be used regularly over an extended period, and the article, by reason of its laxative properties, was not suitable for such use; Section 502 (e) (2), the label failed to bear a statement of the quantity or proportion of strychnine in the article, since the label statement, "containing .038 grains of strychnine alkaloid per fluid oz.," was incorrect; Section 502 (f) (1), the article was represented as a stomachic, and the labeling failed to bear adequate directions for use as such; and, Section 502 (f) (2), the labeling failed to bear adequate warnings against unsafe methods or duration of administration of the article, since it failed to warn that, when taken frequently or continuously, as was provided by the directions, such use may result in dependence upon laxatives to move the bowels.

**DISPOSITION:** September 13, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1809. Misbranding of an unlabeled drug. U. S. v. 1,944 Bottles of an Unlabeled Drug. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 16713. Sample No. 4166-H.)**

**LIBEL FILED:** July 26, 1945, Eastern District of Pennsylvania.

**ALLEGED SHIPMENT:** On or about April 25, 1945, from Camden, N. J., by the Aid Laboratories.

**PRODUCT:** 1,944 unlabeled 3-ounce bottles of a drug consisting of a solution of epsom salt, iron chloride, a small proportion of a citrate, and a trace of quinine in glycerin and water, at Philadelphia, Pa.

**NATURE OF CHARGE:** Misbranding, Section 502 (b), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and it failed to bear an accurate statement of the quantity of the contents; Section 502 (e) (2), it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f), the article was essentially a laxative, and its labeling failed to bear any directions for use; and it also failed to warn that the article should not be taken in case of nausea, vomiting, abdominal pain, or other symptom of appendicitis, and that frequent or continued use of the article may result in dependence upon laxatives to move the bowels.

**DISPOSITION:** October 11, 1945. The Union Drug Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for labeling under the supervision of the Federal Security Agency.

**1810. Misbranding of BF-1 Tablets. U. S. v. 598 Bottles and 16 Bottles of BF-1 Tablets, and 5,000 leaflets. Default decree of condemnation and destruction. (F. D. C. No. 16712. Sample Nos. 27842-H, 27843-H.)**

**LIBEL FILED:** August 18, 1945, Western District of Washington.

**ALLEGED SHIPMENT:** Between the approximate dates of June 23, 1944, and April 2, 1945, by the Vegetrates Co., from Los Angeles, Calif.

**PRODUCT:** 598 100-tablet bottles and 16 450-tablet bottles of *BF-1 Tablets*, and 5,000 leaflets entitled "Vegetrates," at Seattle, Wash. Examination showed that the product consisted of ground plant material, including senna, alfalfa, starch, Irish moss, dulse, yeast, and parsley.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the words "Average Ration," borne on the bottle label, and certain statements in the leaflets, were misleading since they represented and suggested that the article was a food, whereas it was not a food, but a laxative drug; and the following statements in the leaflet were false and misleading since a senna laxative is not capable of producing the benefits claimed: "Use Vegetrates BF-1 and Live, Work, Play Every Day. Don't let restless nights spoil your tomorrows. That glorious feeling of waking up each morning ready to start the day with a song! No putting off appointments, turning down 'dates,' neglecting work because you are 'all in,' have a headache, or feel bad. You, too, can enjoy the sparkling, vibrant freshness each morning by being 'regular.' When that slightest feeling of heaviness, or that 'clogged up' feeling comes, try Vegetrates BF-1, used as directed on label."

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe methods or duration of administration, since the warning appearing on the label, "do not use a laxative continuously as there is a possibility of it becoming habit forming," had been made

inadequate by the directions, "2 or 3 tablets morning and night," which provided for using a laxative continuously.

**DISPOSITION:** October 11, 1945. No claimant having appeared, judgment of condemnation was entered and the product, together with the leaflets, was ordered destroyed.

**1811. Misbranding of Sa-Vi-Ade. U. S. v. 500 Bottles of Sa-Vi-Ade, and 500 circulars. Default decree of condemnation and destruction.** (F. D. C. No. 19081. Sample No. 2977-H.)

**LABEL FILED:** February 1, 1946, District of Columbia.

**PRODUCT:** 500 bottles of *Sa-Vi-Ade*, held for sale at the G. C. Murphy Co., Washington, D. C., together with approximately 500 accompanying circulars entitled "Take your place in the Sun with Sa-Vi-Ade."

**LABEL, IN PART:** "Sa-Vi-Ade contains: Fish liver oil concentrates—Thiamin Hydrochloride—Riboflavin, Niacin, Calcium Pantothenate, Pyridoxine, Ascorbic Acid, Irradiated Yeast, Wheat Germ Oil, Soy Bean, Malt Extract, Brewer's Yeast, Dicalcium Phosphate, Iron Byhydrogen, Potassium Iodide, Copper, Zinc, Cobalt, Manganese and Magnesium Sulphates, Sodium Carbonate, Sulphur, Gum Karaya, Sugar and synthetic flavors with color added, Dextrose."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the label and in the circulars were false and misleading, since they represented and suggested that the article would be effective for imbuing the user with robust health; that common foods, such as fruits and vegetables, are not satisfactory sources of the vitamins and minerals essential in human nutrition; that leading authorities agree that 99 percent of the American people are deficient in minerals; that it is very difficult, if not impossible, to obtain adequate amounts of vitamins and minerals from common foods; and that it is important, if not absolutely necessary, to supplement the diet with a product such as *Sa-Vi-Ade* in order to prevent illness, disease, and impaired health. The article would not be effective for imbuing the user with robust health; common foods are satisfactory sources of vitamins and minerals essential in human nutrition; leading authorities do not agree that 99 percent of the American people are deficient in minerals; it is not impossible nor difficult to obtain adequate amounts of vitamins and minerals from a diet of common foods; and it is not ordinarily necessary or important to supplement the diet with a product such as *Sa-Vi-Ade* to prevent illness, disease, or impaired health.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of arthritis, neuritis, rheumatism, rheumatic fever, sickness, and tiredness; for preventing colds; for improving eyesight; for effecting normal elimination; and for overcoming 85 percent of human aches and pains, which are the diseases, symptoms, and conditions for which the article was offered in its advertising disseminated and sponsored by and on behalf of its manufacturer or packer.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

**DISPOSITION:** March 22, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1812. Misbranding of Williams Foot Balm. U. S. v. 492 Jars of Williams Foot Balm. Default decree of condemnation and destruction.** (F. D. C. No. 19738. Sample No. 18344-H.)

**LABEL FILED:** May 2, 1946, Southern District of Ohio.

**ALLEGED SHIPMENT:** On or about March 22, 1946, by the Newman Products Co., from Brooklyn, N. Y.

**PRODUCT:** 456 4-ounce jars and 36 12-ounce jars of *Williams Foot Balm* at Cincinnati, Ohio. Examination showed that the product consisted essentially of stearic acid, volatile oils, including methyl salicylate, and  $\frac{1}{4}$  percent of borax.

The following statements were made by a representative of the shipper in a lecture given in promoting the sale of the product at Cincinnati, Ohio: "When pores are clogged with dead skin, the poison and acid cannot come out, but goes in and causes neuritis, or goes into the bones and causes arthritis. Don't be afraid to apply this Foot Balm any place—on the face, hands, etc."